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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,969	03/21/2000	Jan Gelichter	96700/596	6902

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01/30/2004

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/531,969	Applicant(s) GELIEBTER ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- **Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-54, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 55-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0503</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment received on 11/6/03 has been entered. Claims 50-59 are pending and are under current examination.

Sequence Compliance

The instant application is now in sequence compliance.

Information Disclosure Statement

The second page of the IDS received on 5/20/03 has been initialed and the references disclosed therein considered. A copy of the initialed page is attached to the instant Office action. The Examiner regrets any confusion resulting from the inadvertent omission of said page from the previous Office action.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-54 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is

maintained for the reasons of record advanced on pages 3-4 of the Office action mailed on 8/13/03.

Claims 50-54 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods to the extent of nucleotide sequences encoding potassium channel proteins that are K_{ATP} or maxi-K, does not reasonably provide enablement for all other methods embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection is maintained for the reasons of record advanced on pages 5-6 of the Office action mailed on 8/13/03.

Applicant's arguments, directed to both of the above rejections, received on 11/6/03 have been fully considered but are not found persuasive. Applicants assert that the instant specification does not contemplate limiting the instantly claimed invention to maxi-K and K_{ATP} . Applicants assert the instant specification is replete with numerous references to the use of exogenous potassium channels generally in connection with corporeal smooth muscle and for the treatment of erectile dysfunction. See for example, page 21, lines 11-21, page 19, lines 10-17, page 20, lines 5-6, page 27, lines 16-19, page 68, lines 22-25, and page 78, lines 23-27. See pages 4-8 of the amendment.

In response, the Examiner maintains that potassium channel proteins, other than K_{ATP} or maxi-K channel, were not described or embraced or considered enabled by the instant specification as the instant specification has stated only K_{ATP} or maxi-K are

present or physiologically relevant with respect to corporal smooth muscle. See pages 3-6 of the Office action mailed on 8/13/03. In particular, the rejections are maintained because the specification has discussed on page 27, in lines 24-28 that "despite the plethora of known K⁺ channel subtypes, experimental and clinical data in human corporal smooth muscle provide evidence for the presence and physiological relevance of only two: (1) the metabolically-gated K⁺ channel (i.e., K_{ATP}), and (2) the large-conductance, calcium-sensitive K⁺ channel (i.e., the K_{Ca} or maxi-K channel)." The passages of the specification cited by Applicants in support of their arguments do not appear to provide any further evidence of other potassium channel proteins physiologically relevant for regulation of penile smooth muscle. For example, page 21 at lines 11-21 merely provides a general description of the invention; page 19 at lines 10-17 merely lists various proteins thought to regulate smooth muscle tone but with regard to potassium channels only maxi-K and K_{ATP} are listed; page 20 at lines 5-6 only discusses maxi-K and K_{ATP}; page 27 at lines 16-19 merely discusses the identification of more than thirty potassium channels expressed in smooth muscle however with respect to corporal smooth muscle lines 24-28 appear to suggest that only maxi-K and K_{ATP} are relevant; page 68 at lines 22-25 provides a discussion related to maxi-K; and page 78 at lines 23-27 provides no further evidence of other relevant potassium channel proteins as only maxi-K and K_{ATP} are mentioned.

The lack of relevant support provided by the instant specification appears to suggest to the skilled artisan that other K⁺ channels may not be embraced by the invention and that Applicants were not in possession of the other K⁺ channels at the

time the invention was made. Moreover, it appears from the lack of guidance provided by the instant specification that the other K⁺ channels embraced by the claims were outside the scope of the enabled invention at the time the invention was made. It is maintained the instant specification has not provided adequate guidance, teachings, or working examples that demonstrate or otherwise correlate to use of the other K⁺ channel proteins when practicing the methods as claimed.

Accordingly, the rejections are maintained for the reasons of record.

Allowable Subject Matter

Claims 55-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER

A handwritten signature in cursive script that reads "Pete Paras".